Applicants note that the Gasson reference may have been missing one or two pages. As Applicants are not sure whether said pages were missing, another copy of this reference is attached to this response.

IN THE TITLE

See attached

Please cancel the title and replace it with the following:

-- A NASAL SPRAY FOR TREATING STREPTOCOCCAL INFECTIONS--

IN THE CLAIMS

See attached.

IN THE ABSTRACT

Please see attachment

RESPONSE

Applicants have amended the claims in response to the Office Action. Claims 1-7, 9, 20-45, and 47 have been canceled the other claims have been amended. 35 USC 112 objections have been addressed.

The claim relating to mammals has been deleted.

Additionally, as the claims are now written, there are no 35 USC 102 or 35 USC 103 issues remaining.

Ogawa does not teach or suggest a nasal spray containing a lytic enzyme (used for the purposes) for treating a *Streptococcus* infection. Similarly, Sokawa makes no mention of a nasal spray, nor does Raina or Fischetti.

More specifically, Fischetti (5,604,109), nor any combinations of the prior art with Fischetti, teaches a nasal spray. In fact, no mention is made of a nasal spray. A nasal spray includes includes many other compounds besides a lytic enzyme. It is an aerated spray, containing a number of components, held in a special container, geared to distribute the lytic enzyme into the patient's nose. This is a unique composition in and of itself, which happens to contained a Streptococcal lytic enzyme.

The Office Action also rejects the "old" claims on the basis of double patenting. However, 804 II A states:

> A reliable test for double patenting under 35 U.S.C. 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Is there an embodiment of the invention that falls withing the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would nto exist. For example, the invention defined by a claim reciting a compund having a "halogen"substituent is not identical to or substantively the same as a claim reciting the same compound except having a "chlorine"substituent in place of the halogen because "halogen"is broader than "chlorine." On the other hand, claims may be differently worded and still define the same invention. Thus a claim reciting a widget having a length of "36 inches" defines the same invention as a claim reciting the same widget having a length of "3 feet."

Thus, according to the "negative definition" found in the USPTO and as determined by the courts, the claims as presently written do not rise to the level of "double patenting."

Applicants will acknowledge that there **may be** "obviousness double patenting." A terminal disclaimer will be prepared upon agreement of the claims in question or their possible subsequent amended progeny in this application.

The application is now in condition for allowance. Please call the undersigned at (301) 603-9071 if you have any questions or comments. Thank you.

Very truly yours,

Jonathan E. Grant

Reg. No. 34,830

2107 Hounds Run Place
Silver Spring, Maryland 20906

IN THE TITLE

Please cancel the title and replace it with the following:

-- A NASAL SPRAY FOR TREATING STREPTOCOCCAL INFECTIONS–

IN THE CLAIMS

Please amend the following claims:

Claims 1-7) (Previously canceled)

Claim 8) (currently amended) A [pharmaceutical composition] nasal spray for treating a streptococcal infection, comprising

(i) an effective amount of a lysin enzyme genetically coded for by a C1 bacteriophage capable of infecting a group C Streptococcal bacteria , said lysin enzyme characterized by the ability to [specifically] destroy only the cell wall of a bacteria selected from the group consisting of of Group A Streptococci, Group C Streptococci, and Group E Streptococci,; and

(ii) a nasal spray carrier for delivering said lysin enzyme to a[mouth, throat,] or nasal passage.

Claim 9) (canceled)

Claim 10) (currently amended) The [composition] nasal spray according to claim 8, further comprising a buffer that maintains pH of the [composition] nasal spray at a range between about 4.0 and 9.0.

Claim 11. (currently amended) The [composition] nasal spray according to claim 10, wherein said buffer maintains the pH of the [composition] nasal spray at range between 5.5 and 7.5.

Claim 12. (currently amended) The [composition] nasal spray according to claim 10, wherein said buffer comprises a reducing agent.

Claim 13. (currently amended) The [composition] nasal spray according to claim 12, wherein said reducing agent is dithiothreitol.

Claim 14. (currently amended) The [composition] nasal spray according to claim 10, wherein said buffer comprises a metal chelating agent.

Claim 15. (currently amended) The [composition] nasal spray according to claim 14, wherein said metal chelating agent is ethylenediaminetetraacetic disodium salt.

Claim 16. (currently amended) The [composition] nasal spray according to claim 10, wherein said buffer is a citrate-phosphate buffer.

Claim 17. (currently amended) The [composition] nasal spray according to claim 8, further comprising a bactericidal or bacteriostatic agent as a preservative.

Claim18. (currently amended) The [composition] nasal spray according to claim 8, wherein said lysin enzyme is lyophilized.

Claim 19. (currently amended) The [composition] nasal spray according to claim 9, wherein said carrier further comprises a sweetener.

Claims 20 - 45. (canceled)

Claim 46. (currently amended) The [composition] nasal spray according to claim 8, wherein said carrier is suitable for delivering said lysin enzyme to the nasal passage.

Claim 47. (canceled)

IN THE ABSTRACT

A nasal spray for treating a streptococcal infection is disclosed. The spray comprises an effective amount of a lysin enzyme genetically coded for by a C1 bacteriophage capable of infecting a group C Streptococcal bacteria , and a nasal spray carrier for delivering said lysin enzyme to a mouth, throat, or nasal passage.